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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,268	01/05/2006	Rajendra Narayanrao Kankan	TPP 31771	5107
24257 7590 11/13/2007 STEVENS DAVIS MILLER & MOSHER, LLP			EXAMINER	
1615 L STREET, NW SUITE 850			MORRIS, PATRICIA L	
WASHINGTON, DC 20036		ART UNIT	PAPER NUMBER	
			1625	
			MAIL DATE	DELIVERY MODE
			11/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	•	Application No.	Applicant(s)			
Office Action Summary		10/542,268	KANKAN ET AL.			
		Examiner	Art Unit			
		Patricia L. Morris	1625			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)⊠	Responsive to communication(s) filed on 30 Ju	<i>ıly</i> 2007.				
2a)⊠	This action is FINAL . 2b) This action is non-final.					
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
4)🖂	4)⊠ Claim(s) <u>1-8 and 10-13</u> is/are pending in the application.					
	4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.						
· · · · · · · · · · · · · · · · · · ·	Claim(s) <u>1-8 and 10-13</u> is/are rejected.	•				
• —	Claim(s) is/are objected to.					
8)	Claim(s) are subject to restriction and/o	r election requirement.				
Applicati	ion Papers					
9)	The specification is objected to by the Examine	er.				
10)	The drawing(s) filed on is/are: a) acc					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority (under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
	3. Copies of the certified copies of the priority documents have been received in this National Stage					
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
A44.c = b	.4(a)					
Attachmen	nt(s) be of References Cited (PTO-892)	4) 🔲 Interview Summa	ury (PTO-413)			
2) Notice	ce of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail	Date			
3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 5) Notice of Informal Patent Application 6) Other:						

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DETAILED ACTION

Claims 1-8 and 10-13 are under consideration in this application.

The rejections under 35 USC 102 and 103 are hereby withdrawn in view of applicants' arguments in the instant response filed on July 30, 2007.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Again, there is a lack of description as to how the solvates and hydrates are produced and what solvates and hydrates are produced in the specification. Applicants point out to pages in the specification to show description. However, no where in specification do applicants prepare any solvates or hydrates or identify any by X-ray diffraction data.

The newly added references are cited as to showing the state-of-the art. Vippagunata et al. (Advanced Drug Devlivery Reviews 48 (2001) 3-26) recites on page 18 that predicting the formation of solvates of a compound and the number of molecules of solvent or water

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incorporated into the crystal lattice of a compound is complex and difficult. Guillory (in Brittain et al., NY:Marcel Dekker, 1999, pages 183-226, teach that solvates are formed by recrystallization of drug substances. However, not all compounds will form solvates.

Predicting the formation of solvates and hydrates of a compound and the number of molecules of solvent incorporated into the crystal lattice of a compound is complex and difficult. Each solid compound responds uniquely to the possible formation of solvates or hydrates and hence generalizations cannot be made for a series of compounds. Note section 3.4 of Vippaguanta et al.

The working examples in the specification fail to show how any solvates and hydrates are produced. Further, Guillory on page 199 recites that compounds originally crystallized as solvates can lose the solvent induced by heat or vacuum vaporization.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Again. the term converting in claim 1 does not clearly define a process. Applicants merely allege that the term is conventional. However, salt formation is an obvious process under 35 U.S.C. 103. How are the salts, hydrates or solvates formed? The term "converting" renders the claims indefinite and based on an inadequate or insufficient disclosure by placing no definite limits or boundaries in the claim. "Converting" does not signify that a reaction has taken place and should accordingly be changed to reacting

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Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia L. Morris whose telephone number is (571) 272-0688. The examiner can normally be reached on Mondays through Fridays.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia L. Morris Primary Examiner Art Unit 1625

plm November 8, 2007